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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,437	04/25/2007	Paolo Costantino	PAT051825-US-PCT	9723

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	PAPER NUMBER
1645	

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04/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,437	COSTANTINO ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-23,25 and 27* is/are pending in the application.

4a) Of the above claim(s) *2,9,24 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-8, 11-13 and 14-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response and amendment to the claims filed 2-11-2011 has been entered into the record. Claims 1-9, 11-23, 25 and 27 are pending. Claims 10, 24 and 26 have been cancelled.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings

The drawings in this application have been accepted. No further action by Applicant is required.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-12, species W135 in the response filed 2-11-2011 is acknowledged. The traversal is on the ground(s) that the strains or degree of acetylation is not provided by the 'WO03/007985 document. This is not found persuasive because the capsular polysaccharide is purified and conjugated from the same microorganism W135 by the identical process. Applicants assert that strain differences in O-acetylation occur. This is not persuasive as the specification does not demonstrate strain differences and the specification does not direct one to any particular

W135 strain, nor identify such as critical, furthermore the art teaches the 5554 strain (page 20). The specification teaches that any W135 seorgroup can be used. As such, the claims lack a technical feature over the prior art, as the specification merely characterizes the capsular polysaccharide o-acetylation status obtained and made by the prior art.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2, 9, 24 and 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response filed 2-11-2011.

Claim Objections

Claims 13-23 are objected to because of the following informalities: the claims are objected to as depending from non-elected subject matter. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1, 3-8, 11-13 and 14-18 and 20-23 are directed to an invention not patentably distinct from the W135 conjugate product claims of commonly assigned 12/351,281; 12/321,464 and 12/321,420. Specifically, because the W135 conjugates claimed anticipate the instantly claimed conjugates as they are made by the same method using the same starting products and as such the products of the prior application necessarily have the recited acetylated structure.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 12/351,281; 12/321,464 and 12/321,420, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the

commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of copending Application No. 12/351,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because the W135 conjugates claimed anticipate the instantly claimed conjugates as they are made by the same method using the same starting products and as such the products of the prior application necessarily have the recited acetylated structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-44 of copending Application No. 12/321,464. Although the conflicting claims are not identical, they are not patentably distinct from each other because the W135 conjugates claimed anticipate the instantly claimed conjugates as they are made by the same method using the same starting products and as such the products of the prior application necessarily have the recited acetylated structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34 and 67 of copending Application No. 12/321,420. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

W135 conjugates claimed anticipate the instantly claimed conjugates as they are made by the same method using the same starting products and as such the products of the prior application necessarily have the recited acetylated structure.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102 or 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the

> requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 03/007985 published 30 January 2003.

WO 03/007985 teaches the conjugation of *N. meningitidis* serotype W135 capsular polysaccharide to CRM197 (see pages 16-17). The W135 purification and conjugation resulted in oligosaccharides with an average degree of polymerization of about 15 to 20. The isolation and conjugation procedures are identical to that which was employed in the instant specification and the specification teaches that the W135 capsular polysaccharides were purified and conjugated as identically described in WO 03/007985 (see pages 24-26 of the instant specification). WO 03/007985 teaches the conjugate of W135 with CRM197 can be combined with other conjugates (see page 22). The conjugates may be provided in lyophilized or liquid forms (see page 8). WO 03/007985 teaches the conjugates may be combined with other non-meningococcal or non-neisserial antigens and preferred to include proteins from serogroup B of *N. meningitidis* (see page 6, line 10-page 7, line 30). Antigens from pneumococcus, hepatitis A virus, hepatitis B virus, *B. pertussis*, diphtheria, tetanus, H. pylori, polio and/or *H. influenzae* are particularly preferred.

Applicant's arguments have been considered but are not persuasive. It is Applicants burden to establish that the product of the prior art is different than the instantly claimed product. The specification does not teach that there is wide variation in the O-actetylation of W135 polysaccharide, but merely finds that it is not well characterized (see specification page 1, line 15- page 2, line 15). The specification does not describe the criticality of any W135 strain. Instead, the specification teaches that "Relative to unmodified saccharides, derivatives of the invention are preferentially selected during the conjugation to carrier proteins." (page 2, lines 22-23). As the instantly claimed conjugates are made by the identical process as the prior art, the compositions of the prior art necessarily have the recited structures present and uses the

same strain W135 5554 see data at pages 20 and 27. Therefore, unlike applicants assertion that the criticality is the strain, the specification teaches that it is the conjugation that is critical and the prior art teaches the identical conjugation protocol with the identical strain. Therefore, the structure is inherent to the conjugate of the prior art.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Constantino (US 2009/0117148, with priority to June 20, 2002) or Constantino US 2009/0182129, with priority to June 20, 2002) or Constantino (US 2009/0130147, with priority to June 20, 2002) or Constantino (US 2005/0106181, with priority to June 20, 2002).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Each of Constantino teaches the conjugation of *N. meningitidis* serotype W135 capsular polysaccharide to CRM197. The W135 purification and conjugation resulted in oligosaccharides with an average degree of polymerization of about 15 to 20. The isolation and conjugation procedures are identical to that which was employed in the instant specification and the specification teaches that the W135 capsular polysaccharides were purified and conjugated as identically described in the US publications (see pages 24-26 of the instant specification). Each of Constantino teaches the conjugate of W135 with CRM197 can be combined with other conjugates (see page 22). The conjugates may be provided in lyophilized or liquid forms (see page 8). Each of Constantino teaches the conjugates may be combined with other non-meningococcal or non-

neisserial antigens and preferred to include proteins from serogroup B of *N. meningitidis* (see page 6, line 10- page 7, line 30). Antigens from pneumococcus, hepatitis A virus, hepatitis B virus, *B. pertussis*, diphtheria, tetanus, H. pylori, polio and/or *H. influenzae* are particularly preferred. The references inherently anticipate the instant claims.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 03/007985 published 30 January 2003 in view of WO 03/080678, published October 2, 2003, filed March 23, 2003).

WO 03/007985 teaches the conjugation of *N. meningitidis* serotype W135 capsular polysaccharide to CRM197 (see pages 16-17). The W135 purification and conjugation resulted in oligosaccharides with an average degree of polymerization of about 15 to 20. The isolation and conjugation procedures are identical to that which was employed in the instant specification and the specification teaches that the W135 capsular polysaccharides were purified and conjugated as identically described in WO 03/007985 (see pages 24-26 of the instant specification). WO 03/007985 teaches the conjugate of W135 with CRM197 can be combined with other conjugates (see page 22). The conjugates may be provided in lyophilized or liquid forms (see page 8). WO 03/007985 teaches the conjugates may be combined with other non-meningococcal or non-neisserial antigens and preferred to include proteins from serogroup B of *N. meningitidis* (see page 6, line 10-page 7, line 30). Antigens from pneumococcus, hepatitis A virus, hepatitis B virus, *B. pertussis*, diphtheria, tetanus, H. pylori, polio and/or *H. influenzae* are particularly preferred. WO 03/007985 differs by not teaching serogroup A antigen has blocking groups, However, WO 03/007985 teaches that serogroup A antigen suffers from hydrolysis and lack of stability.

WO 03/080678 teaches blocking group protection of serogroup A antigen solves the problem of hydrolysis and provides such in conjugates.

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to substitute the serogroup A antigen conjugate of WO 03/080678 for the serogroup A antigen conjugate of WO 03/007985 because WO 03/080678 teaches that the blocked serogroup A antigen has improved stability.

Status of the Claims

Claims 1, 3-8, 11-13 and 14-23 stand rejected. All other claims are withdrawn or cancelled.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-Th 6:30 am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor Gary Nickol can be reached at 571-272-0835.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Patricia A. Duffy/
Primary Examiner